

Remarks

This responds to the Office Action dated February 12, 2007.

Claims 1, 14, 16, 25-26, 32, 35, 39 and 44 are amended and claims 12-13, 27-29 and 41-43 are canceled. Claims 1-11, 14-26, 30-40 and 44-45 are pending in this application.

The 35 U.S.C. § 112, Second Paragraph, Rejection

Claim 44-45 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicant has amended claim 44 to overcome this rejection.

The 35 U.S.C. § 102 Rejections

Claims 1 and 3 were rejected under 35 U.S.C. § 102(b) as being anticipated by Vachon et al. (U.S. Patent No. 5,324,324). Applicant respectfully traverses the anticipation rejection of claims 1 and 3.

“Anticipation requires the presence in a single prior reference disclosure of each and every element of the claimed invention, arranged as in the claim.” *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983).

Claim 1 recites “[a]n apparatus comprising: an electrical lead comprising a lead body and an electrical conductor; and an electrode coupled to the electrical conductor, wherein the electrode includes a coating on at least a portion of a surface of the electrode, the coating including three or more layers, with a first layer adjacent the surface of the electrode including an insulative material and a second layer adjacent the first layer and not adjacent to the surface of the electrode including at least one pharmacological agent, and a third layer above the second layer, wherein the third layer includes at least one pharmacological agent.”

Applicant respectfully submits that the Office Action’s characterization of Vachon et al., in particular the figure on page 5 of the Office Action, is incorrect. In the figure on page 5 of the Office Action, it is noted that “2nd layer not adjacent to the electrode.” However, at column 4, lines 3-20, Vachon et al. disclose that the electrode has a distal tip 60 with a generally mushroom shape. A portion of this distal tip 60 is enlarged in Figure 3 and disclosed to include the base

metallic material **70** (the electrode) and a coating material **72**. Thus, the layer referred to as the second layer (**72**) in the Office Action is adjacent to the electrode.

Therefore, Applicant cannot find in the cited reference: “wherein the electrode includes a coating on at least a portion of a surface of the electrode, the coating including three or more layers, with a first layer adjacent the surface of the electrode including an insulative material and a second layer adjacent the first layer and not adjacent to the surface of the electrode including at least one pharmacological agent...,” as recited in claim 1. Thus, the cited document does not disclose, *inter alia*, a first and second layer arranged as recited in claim 1.

On page 5, the Office Action notes that “the claim does not say...that the second layer is not adjacent the ‘entire’ surface of the electrode.” Applicant notes that claim 1 recites that the second layer is “not adjacent to the surface of the electrode.”

Claim 3 includes each limitation of claim 1 and is therefore also not anticipated by the cited document. Reconsideration and allowance is respectfully requested.

Claims 1, 3-7, 9, 10, 12-16, 18-23, 25, 35-37 and 41-44 were rejected under 35 U.S.C. § 102(b) as being anticipated by Vachon et al. (U.S. Patent No. 6,405,091). Applicant respectfully traverses the anticipation rejection of claims 1, 3-7, 9, 10, 12-16, 18-23, 25, 35-37 and 41-44.

Claims 1 and 3-7

Applicant has amended claim 1 to better describe the subject matter recited in the claim. Applicant believes that claim 1 is not anticipated by the cited document since the document does not include each limitation recited in the claim. For instance, Applicant cannot find in the cited document: wherein the electrode includes a coating on at least a portion of a surface of the electrode, the coating including three or more layers, with a first layer adjacent the surface of the electrode including an insulative material and a second layer adjacent the first layer and not adjacent to the surface of the electrode including at least one pharmacological agent, and a third layer above the second layer, wherein the third layer includes at least one pharmacological agent.”

Claims 3-7 include each limitation recited in claim 1 and are therefore also not anticipated by the cited document. Reconsideration and allowance is respectfully requested.

Claims 9, 10 and 25

Claims 9 and 10 include each limitation recited in claim 1 and are therefore also not anticipated by the cited document.

Claim 16 has been amended to better describe the subject matter recited in the claim. Applicant believes that claim 16 is not anticipated by the cited document since the document does not include each limitation recited in the claim. For instance, Applicant cannot find in the cited document: an electrode coupled to the electrical conductor, wherein an outer surface of the electrode is coated with three or more layers comprising a first layer including an insulative material and a second layer over the first layer, the second layer including at least one pharmacological agent, and a third layer above the second layer, wherein the third layer comprises at least one pharmacological agent. Claim 25 includes each limitation recited in claim 16 and is therefore also not anticipated by the cited documents.

Reconsideration and allowance is respectfully requested.

Claims 12-14

Claims 12-14 have been cancelled.

Claim 15

Claim 15 includes each limitation recited in claim 1 and is therefore also not anticipated by the cited document. Reconsideration and allowance is respectfully requested.

Claims 16, 21, 35, 41 and 44

As discussed above, Applicant believes that claim 16 is not anticipated by the cited document. Claim 21 includes each limitation recited in claim 16 and is therefore also not anticipated by the cited document.

Claim 35 has been amended to better describe the subject matter recited in the claim. Applicant believes that claim 35 is not anticipated by the cited document since the document

does not include each limitation recited in the claim. For instance, Applicant cannot find in the cited document: a method comprising coating an electrode with a first layer, wherein the first layer comprises a polymeric base coat; coating the first layer of the electrode with a second layer, wherein the second layer comprises a polymer and at least one pharmacological agent, and at least partially coats the first layer; and coating the second layer with a third layer, wherein the third layer comprises at least one pharmacological agent. Claim 44 includes each limitation recited in claim 35 and is therefore also not anticipated by the cited document. Claim 41 is cancelled.

Reconsideration and allowance is respectfully requested.

Claims 18-20, 22-23, 36-37 and 42-43

Claims 18-20 and 22-23 include each limitation recited in claim 16, while claims 36-37 and 42-43 include each limitation recited in claim 35 and are therefore not anticipated by the cited document. Reconsideration and allowance is respectfully requested.

Claims 35-45 were rejected under 35 U.S.C. § 102(e) as being anticipated by Hossainy et al. (U.S. 2003/0104028). Applicant traverses the rejection of claims 35-45 since the cited document does not include each limitation recited in the claim. For instance, Applicant cannot find in the cited reference: “a method comprising coating an electrode with a first layer, wherein the first layer comprises a polymeric base coat; coating the first layer of the electrode with a second layer, wherein the second layer comprises a polymer and at least one pharmacological agent, and at least partially coats the first layer; and coating the second layer with a third layer, wherein the third layer comprises at least one pharmacological agent,” as recited in claim 35. In contrast, the cited document discloses that outer layer 9 is an inorganic compound, such as gold and diamond-like carbon. Claims 36-45 include each limitation recited in claim 35 and are therefore not anticipated by the cited document. Reconsideration and allowance is respectfully requested.

The 35 U.S.C. § 103 Rejections

Claims 30, 33 and 34 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Stokes (U.S. Patent No. 4,506,680) in view of Sirhan et al. (U.S. 2003/0083646). Applicant traverses the rejection of claims 30, 33 and 34 since Stokes does not teach or suggest all of the limitations of the rejected claims and the secondary reference, Sirhan et al., does not overcome the deficiencies of the primary reference Stokes.

On page 9 of the Office Action it is stated that Stokes “does not disclose a coating including three or more layers....” The Office Action further states that Sirhan et al. disclose a coating including three or more layers citing to Figures 2I and 2K. Applicant respectfully submits that the cited portion of Sirhan et al. does not disclose a coating including three or more layers. Figure 2I discloses a matrix **40** with a second rate-controlling element **49** formed over the matrix **40**. The rate-controlling element **43** forms the matrix **40** with the therapeutic capable agent **28**. Thus, Figure 2I discloses at most two layers: 1) a matrix **40** and 2) a second rate-controlling element **49** formed over the matrix **40**.

Figure 2K discloses that a first therapeutic capable agent **28** may be present in matrix **40** while a second therapeutic capable agent **50** is in a second matrix **52** formed by the second therapeutic capable agent **50** and a second rate-controlling element **55**. Thus, Figure 2K discloses at most two layers: 1) a matrix **40** and 2) a second matrix **52**.

Additionally, in the cited portions of the references, neither Stokes nor Sirhan et al. disclose or suggest a middle layer; nor do they disclose or suggest an outer layer with only a pharmaceutical agent.

Therefore, Stokes does not teach or suggest all of the limitations of the rejected claims and the secondary reference, Sirhan et al., does not overcome the deficiencies of the primary reference.

Claims 33 and 34 include each limitation recited in their parent claim and are therefore also not obvious in view of the cited references. Reconsideration and allowance is respectfully requested.

Claims 2 and 17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Vachon et al. (U.S. Patent No. 6,405,091) as discussed above. Claims 2 and 17 include each limitation of their parent claims (claims 1 and 16, respectively) and are not obvious over the cited reference since the cited reference does not teach or suggest all of the limitations of the rejected claims. Reconsideration and allowance is respectfully requested.

Claims 8, 11, 24 and 26-29 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Vachon et al. (U.S. Patent No. 6,405,091) as applied to claims 5 and 21 above, and in view of Hossainy et al. (U.S. 2003/0104028). Claims 8, 11, 24 and 26 include each limitation of their parent claims (claim 1 or 16) and are not obvious over the cited references since the secondary reference does not overcome the deficiencies of the primary reference. Claims 27-29 are cancelled. Reconsideration and allowance is respectfully requested.

Claim 31 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Stokes (U.S. Patent No. 4,506,680) and Sirhan et al. (U.S. 2003/0083646). Claim 31 includes each limitation of its parent claim (claim 30) and is not obvious over the cited references since the secondary reference does not overcome the deficiencies of the primary reference discussed above. Reconsideration and allowance is respectfully requested.

Claim 32 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Stokes (U.S. Patent No. 4,506,680) and Sirhan et al. (U.S. 2003/0083646) as applied to claim 30 above, and further in view of MacGregor (U.S. Patent No. 4,281,669). Claim 32 includes each limitation of the parent claim (claim 30) and is not obvious over the cited references since the secondary references do not overcome the deficiencies of the primary reference discussed above. Reconsideration and allowance is respectfully requested.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6905 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 3 day of July 2007.

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